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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/456,110 Χ, 12/07/99 LUO 001/001 **EXAMINER** QM32/0531 KEVIN H. FORTIN HAYES, M BURNS DOANE SWECKER & MATHIS LLP ART UNIT PAPER NUMBER P.O. BOX 1404 ALEXANDRIA VA 22313-1404 3763 **DATE MAILED:** 05/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

Office Action Summary		Application No.	Applicant(s)	
		09/456,110	LUO ET AL.	
		Examiner	Art Unit	
		Michael J Hayes	3763	
 Period for	The MAILING DATE of this communication app Reply	ears on the cover sheet with the co	orrespondence address	
THE M - Extens after S - If the p - If NO p - Failure - Any re	PRTENED STATUTORY PERIOD FOR REPLIALING DATE OF THIS COMMUNICATION. Sions of time may be available under the provisions of 37 CFR 1.1 (X) (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a replied for reply within the set or extended period for reply will, by statute ply received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	136 (a). In no event, however, may a reply be till be to the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from be cause the application to become ABANDONE	mely filed s will be considered timely. the mailing date of this communi D (35 U.S.C. § 133).	ication.
1)⊠	Responsive to communication(s) filed on <u>07</u>	December 1999		
2a)□		his action is non-final.		
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Dispositio	on of Claims			
4)⊠ Claim(s) <u>1-44</u> is/are pending in the application.				
4a) Of the above claim(s) is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.				
6) Claim(s) is/are rejected.				
7) Claim(s) is/are objected to.				
8) 🛛 (	Claims <u>1-44</u> are subject to restriction and/or	election requirement.		
Applicatio	on Papers			
9) The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are objected to by the Examiner.				
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.				
12) The oath or declaration is objected to by the Examiner.				
Priority ur	nder 35 U.S.C. § 119			
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:				
1. Certified copies of the priority documents have been received.				
2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).				
Attachment(	s)			
15) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	19) Notice of Informa	rry (PTO-413) Paper No(s) I Patent Application (PTO-15	

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1 drawn to a method of inducing hypothermia, classified in class 604, subclass 500.
  - II. Claims 2, 3 drawn to monitoring a patient's blood pressure, classified in class604, subclass 500.
  - III. Claims 6 and 7 drawn to administering sedative, classified in class 604, subclass 508.
  - IV. Claim 8, drawn to intubating and ventilating a patient, classified in class 604, subclass 500.
  - V. Claim 9 drawn to administering a paralytic drug, classified in class 604, subclass 508.
  - VI. Claim 10 drawn to administering a neuro-protectant, classified in class 604, subclass 508.
  - VII. Claim 11, drawn to performing a neuro-protectant procedure, classified in class 604, subclass 500.
  - VIII. Claim 12, drawn to performing a non-catheter-based hypothermia procedure, classified in class 604, subclass 508.
  - IX. Claim 13, drawn to CSF drainage procedure, classified in class 604, subclass 508.
  - X. Claims 16, 17 drawn to administering an anti-clot or clot lysis drug, classified in class 604, subclass 508.

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- XI. Claims 18, drawn to performing an angioplasty procedure, classified in class 606 subclass 7.
- XII. Claim 19, drawn to performing a stent placement procedure, classified in class 606 subclass 194.
- XIII. Claim 20, drawn to performing a clot removing procedure, classified in class 128 subclass 898.
- XIV. Claim 21, drawn to monitoring ICP, classified in class 128, subclass 898.
- XV. Claim 22, drawn to maintaining ICP, classified in class 128 subclass 898.
- XVI. Claim 23, drawn to administering a paralytic drug, classified in class 604, subclass 508.
- XVII. Claim 24, drawn to administering a neuro-protectant, classified in class 604, subclass 508.
- XVIII. Claim 25, drawn to performing a neuro-protectant procedure, classified in class 604, subclass 500.
- XIX. Claim 26, drawn to performing a non-catheter-based hypothermia procedure, classified in class 604, subclass 508.
- XX. Claim 27, drawn to CSF drainage procedure, classified in class 604, subclass 508.
- XXI Claims 30 and 31, drawn to administering an anti-clot or clot lysis drug, classified in class 604, subclass 508.
- XXII. Claim 32, drawn to performing an angioplasty procedure, classified in class 606 subclass 7.

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- XXIII. Claim 33, drawn to performing a stent placement procedure, classified in class 606 subclass 194.
- XXIV. Claim 34, drawn to performing a clot removing procedure, classified in class 128 subclass 898.
- XXV. Claims 35, 43, and 44, drawn to a system for treating a stroke patient including a cooling catheter, classified in class 604, subclass 113.
- XXVI. Claims 36-40, drawn to a system for treating a stroke patient including a drug delivery compartment, classified in class 604, subclass 113.
- XXVII. Claim 41, drawn to a system for treating a stroke patient including a ventilator, classified in class 604, subclass 113.
- XXVIII. Claim 42, drawn to a system for treating a stroke patient including a cranial pressure probe, classified in class 604, subclass 113.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions II-XXIV and are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions have separate utility such as a method not requiring the procedure or drug of the other inventions. See MPEP § 806.05(d).
- 3. Inventions XXVI-XXVIII and are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions have separate utility such as a system not requiring the particulars of the other inventions. See MPEP § 806.05(d).

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Inventions I and XXV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice a process that cools an internal site, but does not induce hypothermia nor is used in treating stroke patients.

- 5. Because these inventions are distinct for the reasons given above and the search required for one of the groups II-XXIV and XVI-XXVIII is not required for any other of groups II-XXIV and XVI-XXVI respectively, restriction for examination purposes as indicated is proper.
- 6. In addition to the different inventions claimed, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1 drawn to advancing a catheter into a central venous vein.

Species 2 drawn to advancing a catheter into a carotid artery.

Species 3 drawn to a step of draining CSF from a spine cavity.

Species 4 drawn to a step of draining CSF from a brain cavity.

- 7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic to claims 2-34 and claim 35 is generic to claims 36-44.
- 8. The inventions described above are subcombinations that are generically claimed as species under a claimed genus (claim 1 or 35). The restriction is proper both under the practice applicable to related inventions and to election of species. See MPEP 806.04(b) and 806.05(d).

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

- 10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
- 11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel, can be contacted at (703) 308-5115. The fax number for submitting papers is (703) 305-3590.

Michael J. Hayes

Michael & Hayen

29-May-01